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Lupin Ltd. and Lupin Pharmaceuticals, Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, ET AL.,

Plaintiff,

v.

LUPIN LTD., ET AL.,

Defendant.

3:09-CV-05404-JAP-TJB

DOCUMENT FILED ELECTRONICALLY

**ANSWER, DEFENSES AND
COUNTERCLAIMS OF LUPIN LTD AND
LUPIN PHARMACEUTICALS, INC.**

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin Pharma”) (collectively “Defendants” or “Lupin”), by their undersigned counsel, for their Answer to the Complaint of AstraZeneca AB; Aktiebolaget Hassle; AstraZeneca LP; KBI Inc.; and KBI-E Inc. (collectively “Plaintiffs”) state as follows:

JURISDICTION AND VENUE

1. Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants admit that Plaintiffs allege patent infringement and that Plaintiffs rely on the statutes cited in paragraph 1 as the basis for their cause of action, subject matter jurisdiction and venue. Defendants admit that this Court has jurisdiction over the subject

matter of this action.

2. Defendants admit that they submitted Abbreviated New Drug Application (“ANDA”) No. 91-324 seeking the Food and Drug Administration’s (“FDA”) approval to manufacture commercially their proposed 20 mg and 40 mg products called “Esomeprazole Magnesium Delayed Release Capsules (20 mg Base and 40 mg)” (hereinafter referred to as “Esomeprazole Magnesium Capsules”) containing the active ingredient esomeprazole magnesium. Defendants deny the remaining allegations set forth in paragraph 2.

3. Defendants admit the allegations set forth in paragraph 3.

4. Defendants admit that they submitted Abbreviated New Drug Application (“ANDA”) No. 91-324 seeking the Food and Drug Administration’s (“FDA”) approval to manufacture commercially their proposed 20 mg and 40 mg products called “Esomeprazole Magnesium Delayed Release Capsules (20 mg Base and 40 mg)” (hereinafter referred to as “Esomeprazole Magnesium Capsules”) containing the active ingredient esomeprazole magnesium. Defendants further admit that they submitted service of their Notice of Certification. Defendants deny the remaining allegations set forth in paragraph 4.

5. Defendants admit the allegations set forth in paragraph 5.

6. Defendants admit the allegations set forth in paragraph 6.

THE PARTIES

7. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 7.

8. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 8.

9. Defendants deny knowledge of information sufficient to form a belief as to the truth of the

allegations set forth in paragraph 9.

10. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 10.

11. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11.

12. Defendants admit that Lupin Ltd. is a corporation organized and existing under the laws of India, with a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (W), Mumbai, Maharashtra 400 051, India, and with its only places of business located in India. Defendants deny the remaining allegations set forth in paragraph 12.

13. Defendants admit that Lupin Pharma is a Virginia corporation and a wholly-owned subsidiary of Lupin Ltd. having a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, 21202. Defendants deny the remaining allegations set forth in paragraph 13.

14. Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants aver that they consented to personal jurisdiction in New Jersey for the purposes of this litigation only. Defendants deny the remaining allegations in paragraph 14.

UNITED STATES PATENT NO. 5,714,504

15. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 14 as if fully set forth herein.

16. Defendants admit that the issue date set forth on the face of the '504 patent entitled "Compositions" is February 3, 1998. Defendants further admit that the inventors set forth on the face of the '504 patent are Per Lennart Lindberg and Sverker Von Unge and that the assignee set

forth on the face of the patent is Astra Aktiebolag. Defendants further admit that a copy of the '504 patent was attached to the complaint as Exhibit A. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations that the patent was subsequently assigned to AstraZeneca AB. Defendants state that the '504 patent speaks for itself and deny any allegation inconsistent therewith.

17. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17.

18. Defendants admit the allegations set forth in paragraph 18.

19. Paragraph 19 contains legal conclusions to which no answer is required and contains incomplete quotations from various statutes and regulations. To the extent an answer is deemed required, Defendants admit that the quoted language is found in the cited statutes and regulations, admit the allegations contained in the first sentence of paragraph 19 and otherwise deny the allegations set forth in paragraph 19.

20. Defendants admit that they were familiar with the provisions of the statutes and regulations cited in paragraph 19 at the time their Notice of Certification was served and otherwise deny the allegations set forth in paragraph 20.

21. Defendants deny the allegations set forth in paragraph 21.

22. Defendants deny the allegations set forth in paragraph 22.

23. Defendants deny the allegations set forth in paragraph 23.

24. Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin's Esomeprazole Magnesium Capsules, if approved, will be indicated for treatment of gastro esophageal reflux disease; risk reduction of NSAID-associated gastric ulcer; *H. pylori* eradication to reduce risk of duodenal ulcer recurrence;

pathological hypersecretory conditions in humans. Defendants deny the remaining allegations set forth in paragraph 24.

25. Defendants admit that Lupin's Esomeprazole Capsules are will be indicated for treatment of gastro esophageal reflux disease; risk reduction of NSAID-associated gastric ulcer; *H. pylori* eradication to reduce risk of duodenal ulcer recurrence; pathological hypersecretory conditions via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed esomeprazole magnesium and a pharmaceutically acceptable carrier and that Defendants are aware of such. Defendants deny the remaining allegations set forth in paragraph 25.

26. Defendants deny the allegations set forth in paragraph 26.

27. Defendants admit that after a substantial delay, AstraZeneca made unreasonable requests for documents, samples and information and otherwise deny the allegations set forth in paragraph 27.

28. Defendants admit that Lupin's ANDA No. 91-324 and the associated DMF were produced to outside counsel for Plaintiffs on October 9, 2009. Defendants deny the remaining allegations set forth in paragraph 28.

29. Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 29.

UNITED STATES PATENT NO. 5,877,192

30. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 29 as if fully set forth herein.

31. Defendants admit that the issue date set forth on the face of the '192 patent entitled

“Method for the Treatment of Gastric Acid-Related Diseases and Production of Medication Using (-) Enantiomer of Omeprazole” is March 2, 1999. Defendants further admit that the inventors set forth on the face of the ‘192 patent are Per Lindberg and Lars Weidolf and that the assignee set forth on the face of the patent is Astra Aktiebolag. Defendants further admit that a copy of the ‘192 patent was attached to the complaint as Exhibit B. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations that that the patent was subsequently assigned to AstraZeneca AB. Defendants state that the ‘192 patent speaks for itself and deny any allegation inconsistent therewith.

32. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 32.

33. Paragraph 33 contains legal conclusions to which no answer is required and contains incomplete quotations from various statutes and regulations. To the extent an answer is deemed required, Defendants admit that the quoted language is found in the cited statutes and regulations, admit the allegations contained in the first sentence of paragraph 33 and otherwise deny the allegations set forth in paragraph 33.

34. Defendants admit that they were familiar with the provisions of the statutes and regulations cited in paragraph 33 at the time their Notice of Certification was served and otherwise deny the allegations set forth in paragraph 34.

35. Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants aver that the document speaks for itself and refers to the Notice of Certification for its terms, but admit that the Notice does not address non-infringement of claims 12-19 or 21-23 of the '192 patent.

36. Paragraph 36 contains legal conclusions to which no answer is required. To the extent an

answer is deemed required, Defendants deny the allegations set forth in paragraph 36.

37. Defendants deny the allegations set forth in paragraph 37.

38. Defendants deny the allegations set forth in paragraph 38.

39. Defendants deny the allegations set forth in paragraph 39.

40. Paragraph 40 contains legal conclusions to which no answer is required. Defendants admit that Lupin's Esomeprazole Magnesium Capsules, if approved, will be indicated for treatment of gastro esophageal reflux disease; risk reduction of NSAID-associated gastric ulcer; *H. pylori* eradication to reduce risk of duodenal ulcer recurrence; pathological hypersecretory conditions in humans. Defendants admit that the amount to be administered will be between about 20 mg and about 40 mg total daily dose. Defendants deny the remaining allegations set forth in paragraph 40.

41. Defendants admit that Lupin's Esomeprazole Magnesium Capsules, if approved, will be indicated for treatment of gastro esophageal reflux disease; risk reduction of NSAID-associated gastric ulcer; *H. pylori* eradication to reduce risk of duodenal ulcer recurrence; pathological hypersecretory conditions via the administration of a therapeutically effective amount of a pharmaceutical formulation containing esomeprazole magnesium and a pharmaceutically acceptable carrier and that Defendants are aware of such. Defendants deny the remaining allegations set forth in paragraph 41.

42. Defendants deny the allegations set forth in paragraph 42.

43. Defendants deny the allegations set forth in paragraph 43.

44. Defendants admit that after a substantial delay, AstraZeneca made unreasonable requests for documents, samples and information and otherwise deny the allegations set forth in paragraph 44.

45. Defendants admit that Lupin's ANDA No. 91-324 and the associated DMF were produced to outside counsel for Plaintiffs on October 9, 2009. Defendants deny the remaining allegations set forth in paragraph 45.

46. Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 46.

UNITED STATES PATENT NO. 6,875,872

47. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 46 as if fully set forth herein.

48. Defendants admit that the issue date set forth on the face of the '872 patent entitled "Compounds" is April 5, 2005. Defendants further admit that the inventors set forth on the face of the '872 patent are Per Lennart Lindberg and Sverker Von Unge and that the assignee set forth on the face of the patent is AstraZeneca. Defendants further admit that a copy of the '872 patent was attached to the complaint as Exhibit C. Defendants state that the '872 patent speaks for itself and deny any allegation inconsistent therewith.

49. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 49.

50. Paragraph 50 contains legal conclusions to which no answer is required and contains incomplete quotations from various statutes and regulations. To the extent an answer is deemed required, Defendants admit that the quoted language is found in the cited statutes and regulations, admit the allegations contained in the first sentence of paragraph 50 and otherwise deny the allegations set forth in paragraph 50.

51. Defendants admit they were familiar with the provisions of the statutes and regulations

cited in paragraph 50 at the time their Notice of Certification was served and otherwise deny the allegations set forth in paragraph 51.

52. Paragraph 52 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants aver that the document speaks for itself and refers to the Notice of Certification for its terms, but admit that the Notice of Certification does not address non-infringement of claims 1, 2, 4, 5, 7, 8, 10 or 11 of the '872 patent.

53. Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations set forth in paragraph 53.

54. Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations set forth in paragraph 54.

55. Defendants deny the allegations set forth in paragraph 55.

56. Defendants deny the allegations set forth in paragraph 56.

57. Defendants admit the allegations set forth in paragraph 57.

58. Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin's Esomeprazole Magnesium Capsules, if approved will be administered to human patients. Defendants deny the remainder of the allegations set forth in paragraph 58.

59. Defendants admit that Lupin's Esomeprazole Magnesium Capsules are especially made or especially adapted for treatment of humans and that Defendants are aware of this fact. Defendants deny the allegations set forth in paragraph 59.

60. Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants aver that the document speaks for itself and refers to the Notice of Certification for its terms, but admit that the Notice of Certification does not address

non-infringement of Claims 1, 2, 4, 5, 7, 8, 10 or 11 of the ‘872 patent. Defendants deny the remaining allegations set forth in paragraph 60.

61. Defendants deny the allegations set forth in paragraph 61.

62. Defendants admit that after a substantial delay, AstraZeneca made unreasonable requests for documents, samples and information and otherwise deny the allegations set forth in paragraph 62.

63. Defendants admit that Lupin’s ANDA No. 91-324 and the associated DMF were produced to outside counsel for Plaintiffs on October 9, 2009. Defendants deny the remaining allegations set forth in paragraph 63.

64. Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 64.

UNITED STATES PATENT NO. 6,369,085

65. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 64 as if fully set forth herein.

66. Defendants admit that the issue date set forth on the face of the ‘085 patent entitled “Form of S-Omeprazole” is April 9, 2002. Defendants further admit that the inventors set forth on the face of the ‘085 patent are Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller and that the assignee set forth on the face of the patent is AstraZeneca AB. Defendants further admit that a copy of the ‘085 patent was attached to the complaint as Exhibit D. Defendants state that the ‘085 patent speaks for itself and deny any allegation inconsistent therewith.

67. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 67.

68. Paragraph 68 contains legal conclusions to which no answer is required and contains incomplete quotations from various statutes and regulations. To the extent an answer is deemed required, Defendants admit that the quoted language is found in the cited statutes and regulations, admit the allegations contained in the first sentence of paragraph 68 and otherwise deny the allegations set forth in paragraph 68.

69. Defendants admit that they were familiar with the provisions of the statutes and regulations cited in paragraph 68 at the time their Notice of Certification was served and otherwise deny the allegations set forth in paragraph 69.

70. Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations set forth in paragraph 70.

71. Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants aver that the document speaks for itself and refers to the Notice of Certification for its terms, but admit that the Notice of Certification does not address invalidity of the claims of the '085 patent.

72. Defendants deny the allegations set forth in paragraph 72.

73. Defendants deny the allegations set forth in paragraph 73.

74. Defendants deny the allegations set forth in paragraph 74.

75. Paragraph 75 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin's Esomeprazole Magnesium Capsules, if approved, will be indicated for treatment of gastro esophageal reflux disease; risk reduction of NSAID-associated gastric ulcer; *H. pylori* eradication to reduce risk of duodenal ulcer recurrence; pathological hypersecretory conditions in humans. Defendants deny the remaining allegations set forth in paragraph 75.

76. Defendants admit that Lupin's Esomeprazole Magnesium Capsules are indicated for treatment of gastro esophageal reflux disease; risk reduction of NSAID-associated gastric ulcer; *H. pylori* eradication to reduce risk of duodenal ulcer recurrence; pathological hypersecretory conditions in human via the administration of a therapeutically effective amount of a pharmaceutical formulation containing esomeprazole magnesium and that Defendants are aware of this fact. Defendants deny the remaining allegations set forth in paragraph 76.

77. Defendants deny the allegations set forth in paragraph 77.

78. Defendants admit that after a substantial delay, AstraZeneca made unreasonable requests for documents, samples and information and otherwise deny the allegations set forth in paragraph 78.

79. Defendants admit that Lupin's ANDA No. 91-324 and the associated DMF were produced to outside counsel for Plaintiffs on October 9, 2009. Defendants deny the remaining allegations set forth in paragraph 79.

80. Paragraph 80 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 80.

UNITED STATES PATENT NO. 7,411,070

81. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 80 as if fully set forth herein.

82. Defendants admit that the issue date set forth on the face of the '070 patent entitled "Form of S-Omeprazole" is August 12, 2008. Defendants further admit that the inventors set forth on the face of the '070 patent are Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller and that the assignee set forth on the face of the patent is AstraZeneca AB. Defendants

further admit that a copy of the '070 patent was attached to the complaint as Exhibit E. Defendants state that the '070 patent speaks for itself and deny any allegation inconsistent therewith.

83. Defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 83.

84. Paragraph 84 contains legal conclusions to which no answer is required and contains incomplete quotations from various statutes and regulations. To the extent an answer is deemed required, Defendants admit that the quoted language is found in the cited statutes and regulations, admit the allegations contained in the first sentence of paragraph 84 and otherwise deny the allegations set forth in paragraph 84.

85. Defendants admit that they were familiar with the provisions of the statutes and regulations cited in paragraph 84 at the time their Notice of Certification was served and otherwise deny the allegations set forth in paragraph 85.

86. Paragraph 86 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations set forth in paragraph 86.

87. Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants aver that the document speaks for itself and refers to the Notice of Certification for its terms, but admit that the Notice of Certification does not address invalidity of claims of the '070 patent.

88. Defendants deny the allegations set forth in paragraph 88.

89. Defendants deny the allegations set forth in paragraph 89.

90. Defendants deny the allegations set forth in paragraph 90.

91. Defendants lack knowledge of information sufficient to form a belief as to truth of the

allegations set forth in paragraph 91.

92. Defendants lack knowledge or information sufficient to admit or deny the allegations set forth in paragraph 92.

93. Defendants deny the allegations set forth in paragraph 93.

94. Defendants admit that after a substantial delay, AstraZeneca made unreasonable requests for documents, samples and information and otherwise deny the allegations set forth in paragraph 94.

95. Defendants admit that Lupin's ANDA No. 91-324 and the associated DMF were produced to outside counsel for Plaintiffs on October 9, 2009. Defendants deny the remaining allegations set forth in paragraph 95.

96. Paragraph 96 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, defendants deny knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 96.

97. Defendants further answer that any allegations in the Complaint requiring a response from Defendants not specifically admitted are denied.

98. Defendants also deny that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs (a) through (h).

99. Defendants assert that this case is exceptional under 35 U.S.C. § 285.

AFFIRMATIVE DEFENSES

100. Further responding to the Complaint, and as additional defenses thereto, Defendants assert the following affirmative defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on

Plaintiffs.

FIRST AFFIRMATIVE DEFENSE

101. The manufacture, use, offer for sale, sale, or importation of the esomeprazole products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘504 patent.

SECOND AFFIRMATIVE DEFENSE

102. All asserted claims of the ‘504 patent are invalid under 35 U.S.C. §§ 102, 103 or 112.

103. By way of additional example and not of limitation, one or more claims of the ‘504 patent are invalid for the reasons set forth in Lupin’s Notice Letter.

THIRD AFFIRMATIVE DEFENSE

104. The manufacture, use, offer for sale, sale, or importation of the esomeprazole products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘192 patent.

FOURTH AFFIRMATIVE DEFENSE

105. All asserted claims of the ‘192 patent are invalid under 35 U.S.C. §§ 102, 103 or 112.

106. By way of additional example and not of limitation, one or more claims of the ‘192 patent are invalid for the reasons set forth in Lupin’s Notice Letter.

FIFTH AFFIRMATIVE DEFENSE

107. The manufacture, use, offer for sale, sale, or importation of the esomeprazole products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘872 patent.

SIXTH AFFIRMATIVE DEFENSE

108. All asserted claims of the ‘872 patent are invalid under 35 U.S.C. §§ 102, 103 or 112.

109. By way of additional example and not of limitation, one or more claims of the ‘872 patent are invalid for the reasons set forth in Lupin’s Notice Letter.

SEVENTH AFFIRMATIVE DEFENSE

110. The manufacture, use, offer for sale, sale, or importation of the esomeprazole products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘070 patent.

EIGHTH AFFIRMATIVE DEFENSE

111. The manufacture, use, offer for sale, sale, or importation of the esomeprazole products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘085 patent.

COUNTERCLAIMS

112. Further responding to the Complaint, Defendants allege the following counterclaims against AstraZeneca AB; Aktiebolaget Hassle; AstraZeneca LP; KBI Inc.; and KBI-E Inc. (collectively “Plaintiffs”), without admitting any allegation of the Amended Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiffs.

THE PARTIES

113. Lupin Ltd. is a corporation organized and existing under the laws of India, with a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (W), Mumbai, Maharashtra 400 051, India, and with its only places of business located in India.

114. Lupin Pharmaceuticals is a Virginia corporation and a wholly-owned subsidiary of Lupin Ltd. having a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, 21202.

115. Upon information and belief, based on the Complaint, AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. On information and belief, AstraZeneca AB was a corporate name change

from Astra Aktiebolaget.

116. Upon information and belief, based on the Complaint, Aktiebolaget Hassle is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

117. Upon information and belief, based on the Complaint, AstraZeneca LP is a limited partnership organized under the laws of Delaware having its principal place of business at Wilmington, Delaware.

118. Upon information and belief, based on the Complaint, based on the Complaint, AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug Administration ("FDA") for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

119. Upon information and belief, based on the Complaint, KBI Inc. is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

120. Upon information and belief, based on the Complaint, KBI-E Inc. is a Delaware corporation, having its principal place of business at Wilmington, Delaware.

121. On information and belief, based on the Complaint, KBI and KBI-E have exclusive rights in the United States to patents-in-suit.

JURISDICTION AND VENUE

122. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 et seq.

123. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's

jurisdiction seeking a declaratory judgment that the patents are not infringed and are invalid.

124. Venue is proper pursuant to 38 U.S.C. §§ 1391(b) and (c).

THE CONTROVERSY

125. Lupin holds Abbreviated New Drug Application ("ANDA") No. 91-324 for "Esomeprazole Magnesium Delayed Release Capsules (20 mg Base and 40 mg) (hereinafter referred to as "Esomeprazole Magnesium Capsules") containing the active ingredient esomeprazole magnesium.

126. On or about October 21, 2009, Plaintiffs filed the present action against Defendants alleging infringement of the '504, '192, '872, '070, and '085 patents arising from Defendants' submission of ANDA No. 91-324.

COUNTERCLAIM COUNT 1

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '070 PATENT

127. Defendants repeat and incorporate by reference paragraphs 112-126.

128. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '070 patent.

129. The filing of ANDA 91-324 did not infringe the '070 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '070 patent.

130. Because Defendants have not infringed and will not infringe any valid claim of the '070 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 2

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '085 PATENT

131. Defendants repeat and incorporate by reference paragraphs 112-130.
132. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '085 patent.
133. The filing of ANDA 91-324 did not infringe the '085 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '085 patent.
134. Because Defendants have not infringed and will not infringe any valid claim of the '085 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 3

DECLARATORY JUDGMENT OF INVALIDITY OF THE '504 PATENT

135. Defendants repeat and incorporate by reference paragraphs 112-134.
136. All asserted claims of the '504 patent are invalid under 35 U.S.C. §§ 102, 103 or 112.
137. By way of additional example and not of limitation, one or more claims of the '504 patent are invalid for the reasons set forth in Lupin's Notice Letter.
138. Because Defendants have not infringed and will not infringe any valid claim of the '504 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 4

DECLARATORY JUDGMENT OF INVALIDITY OF THE ‘192 PATENT

139. Defendants repeat and incorporate by reference paragraphs 112-138.
140. All asserted claims of the ‘192 patent are invalid under 35 U.S.C. §§ 102, 103 or 112.
141. By way of additional example and not of limitation, one or more claims of the ‘192 patent are invalid for the reasons set forth in Lupin’s Notice Letter.
142. Because Defendants have not infringed and will not infringe any valid claim of the ‘192 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 5

DECLARATORY JUDGMENT OF INVALIDITY OF THE ‘872 PATENT

143. Defendants repeat and incorporate by reference paragraphs 112-142.
144. All asserted claims of the ‘872 patent are invalid under 35 U.S.C. §§ 102, 103 or 112.
145. By way of additional example and not of limitation, one or more claims of the ‘872 patent are invalid for the reasons set forth in Lupin’s Notice Letter.
146. Because Defendants have not infringed and will not infringe any valid claim of the ‘872 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 6

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF

U.S. PATENT NO. 5,690,960

147. Defendants repeat and incorporate by reference paragraphs 112-146.
148. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium

products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘960 patent.

149. The filing of ANDA 91-324 did not infringe the ‘960 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘960 patent.

150. Because Defendants have not infringed and will not infringe any valid claim of the ‘960 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 7

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 5,900,424**

151. Defendants repeat and incorporate by reference paragraphs 112-150.

152. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘424 patent.

153. The filing of ANDA 91-324 did not infringe the ‘424 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘424 patent.

154. Because Defendants have not infringed and will not infringe any valid claim of the ‘424 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 8

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 6,147,103**

155. Defendants repeat and incorporate by reference paragraphs 112-154.
156. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '103 patent.
157. The filing of ANDA 91-324 did not infringe the '103 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '103 patent.
158. Because Defendants have not infringed and will not infringe any valid claim of the '103 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 9

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 6,166,213**

159. Defendants repeat and incorporate by reference paragraphs 112-158.
160. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '213 patent.
161. The filing of ANDA 91-324 did not infringe the '213 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '213 patent.

162. Because Defendants have not infringed and will not infringe any valid claim of the ‘213 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 10

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF

U.S. PATENT NO. 6,191,148

163. Defendants repeat and incorporate by reference paragraphs 112-162.

164. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘148 patent.

165. The filing of ANDA 91-324 did not infringe the ‘148 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘148 patent.

166. Because Defendants have not infringed and will not infringe any valid claim of the ‘148 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

COUNTERCLAIM COUNT 11

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF

U.S. PATENT NO. 6,428,810

167. Defendants repeat and incorporate by reference paragraphs 112-166.

168. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘810 patent.

169. The filing of ANDA 91-324 did not infringe the ‘810 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the ‘810 patent.

170. Because Defendants have not infringed and will not infringe any valid claim of the ‘810 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

PRAAYER FOR RELIEF

WHEREFORE, Defendants seek judgment against Plaintiffs as follows:

- A. That Plaintiffs’ Complaint, and all of its causes of action, be dismissed with prejudice;
- B. That judgment be entered in favor of Defendants, including an Order adjudging U.S. Patent Nos. 5,714,504; 6,875,872; and 5,877,192 invalid; and U.S. Patent Nos. 6,369,085; 7,411,070; 6,147,103; 6,166,213; 6,191,148; 6,428,810; 5,690,690 and 5,900,424 not infringed by Defendants;
- C. That Defendants be awarded their fees and costs in defending this litigation pursuant to 35 U.S.C. § 285; and
- D. That Defendants be awarded such other and further relief as the Court deems just and proper.

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Attorneys for Defendants and Counter-Plaintiffs
Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Dated: December 11, 2009

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Of Counsel

LOCAL RULE 11.2 AND 40.1 CERTIFICATION

Under Local Civil Rules 11.2 and 40.1, the undersigned counsel for Defendants hereby certifies that the matter in controversy in is not the subject of any other action in any court or of any arbitration or administrative proceeding.

Dated: December 11, 2009

By: /s/ Karen A. Confoy
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